REMARKS

Status of the claims and formal matters

Claims 26-37, 39-45 and 51 are pending in the instant application.

Claims 1-25, 38, and 46-50 had been previously cancelled.

Claims 26, 33, 34, 37, 39, 40, and 51 are amended herein. The amendment in question is supported in the specification (WO04/24163), for example, on page 2 (1st full paragraph), on page 7, 4th paragraph and paragraph bridging to page 8. New claim 52 has been added. New claim 52 finds basis in previous claim 37, on page 2, first full paragraph of WO04/24163, and on page 9, second full paragraph of the same. No new matter has been added as a result of these amendments.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims are and were in full compliance with the requirements of 35 U.S.C. § 112.

Examiner Interview

Applicant thanks Examiner Javanmard and Supervising Examiner Padmanabhan for the telephone Interview of February 10, 2011 with Marina Heusch and Paul Prendergast, agent and attorney for Applicant, Richard Clegg, local counsel for Applicant, and Alan Crossman, inventor. During the telephone Interview, it was agreed that Applicant will submit a Declaration with the outstanding response, as well as certain publications referred to by Applicant during the Interview.

Claim rejections under 35 U.S.C. § 103

1. The Examiner maintains her rejection of claims 26-34, 36, 37, 39-45, and 51 under 35 U.S.C. § 103(a) as being unpatentable over Leventer (US 6,649,607 B2) in view of Chenard, *et al.* (EP 0900568 A2). Applicant respectfully disagrees.

In the first, the Examiner admits that "Leventer does not specifically teach treating dyskinesia per se." The Examiner subsequently states that "It would be obvious to one of ordinary skill in the art at the time of the invention to have employed the administration S-tofisopam for the treatment of convulsions or seizures selected from Parkinson's disease, other

neurodegenerative diseases including Huntington's disease, schizophrenia, tics (e.g., Tourette's syndrome) and head injury as taught by Leventer and also used it to treat dyskinesia."; that "As taught by Chenard, dyskinesia is defined as any abnormal or uncontrollable movement including chorea, tremor, dystonia, athetosis, myoclonus and tic."; and that "Thus by administering S-tofisopam, one in essence would have been treating the symptoms that arise from the ailments taught by Leventer of which are specific to dyskinesia, a few of which include tics and myoclonic jerks."

Leventer

Leventer describes compositions comprising and methods of treatment employing S-tofisopam to treat convulsions or seizures in a subject.

Applicant submits herewith a Declaration executed by Dr. Alan Crossman, one of the inventors listed for the instant application. In the Declaration, Dr. Crossman delineates the significant and critical differences between i) convulsions and myoclonic jerks and ii) chorea and dystonia. These differences are pathological, phenomenological, and pharmacological. The person of ordinary skill in the art was, at the time of filing of the instant application, familiar with these differences and would not have reasonably contemplated employing the anti-convulsant tofisopam for the treatment of chorea or dystonia based on its therapeutic efficacy as an anti-convulsant. Doctor Crossman also provides two publications (Chadwick and Montenegro, submitted in Information Disclosure Statement form herewith) showing that anti-convulsants can actually cause dyskinesia manifest as chorea or dystonia, rather than treat it. Of note, Montenegro not only reports her own observations of phenytoin-induced dyskinesias, but also refers to additional reports her group found of 79 patients with dyskinesias induced by phenytoin, as well as reports that involuntary movements have been reported in patients using other anticonvulsants such as carbamazepine and phenobarbitol. Likewise, Chadwick provides, in addition to his own clinical observations, a table listing previous reports of patients with anticonvulsant-induced dyskinesias (Table 1).

Chenard

Chenard is relied upon by the Examiner for its statement that "The term 'dyskinesia(s)', as used herein, unless otherwise indicated, means any abnormal or uncontrollable movement including, but not limited to, chorea, tremor, ballism, dystonia, athetosis, myoclonus and tic."

The term dyskinesia has been deleted from the language of the claims. As a result, the amended claims are directed to the treatment of chorea and/or dystonia, not to the treatment of dyskinesia.

As regards chorea and dystonia, the Examiner states that "...the different categories of dyskinesia are defined as including chorea, dystonia, myoclonus, tremor, etc (according to the website 'answers.com'), Thus, because Leventer teaches that the administration of tofisopam treats convulsions and/or seizures including myoclonic jerks, it would have been obvious to try, with a reasonable degree of success, to administer said drug to treat dyskinesia in view of Chenard's disclosure, which teaches dyskinesia to be 'excessive abnormal movements that are involuntary' including chorea, tremor, dystonia, myoclonus, and tic."

Should the Examiner be maintaining an argument that if a compound treats myoclonic tics, and myoclonic tics are listed as one of a number of abnormal movements included by Chenard under the term dyskinesia, then it should reasonably be expected to treat another abnormal movement -- chorea or dystonia – included by Chenard in that same list, Applicant must disagree.

Atrial fibrillation and pericarditis are both cardiovascular disorders. This certainly does not lead to a reasonable expectation that a therapeutic agent administered for the treatment of atrial fibrillation can be used to likewise treat pericarditis.

As explained by Dr. Crossman in the Declaration filed herewith, myoclonus and epileptic seizures are entirely different conditions from chorea and dystonia. Accordingly, one of skill in the art would not be motivated to employ and anti-convulsant in the treatment of chorea and dystonia, even if the myoclonus, epileptic seizures, chorea, and dystonia are all labeled abnormal movements in a publication.

If an independent claim is non-obvious under 35 U.S.C. § 103, then any claim depending therefrom is non-obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988). Having established the non-obviousness of claim 26, claims 27-34, 37, 37, and 39-45 are, by extension, also non-obvious. Accordingly, Applicant respectfully requests that the instant rejection under 35 U.S.C. § 103 be withdrawn.

2. The Examiner maintains her rejection of claim 35 under 35 U.S.C. § 103(a) as being unpatentable over Leventer (US 6,649,607 B2) in view of Chenard, *et al.* (EP 0900568 A2) and further in view of the "PD website". Applicant respectfully disagrees.

Specifically, the Examiner states that "It would have been obvious to one of ordinary skill in the art at the time of the invention that employing the treatment of dyskinesia associated with parkinsonism as discussed above, that one would have necessarily been treating idiopathic Parkinson's disease."

PD website

The PD website fails to cure the defects of Leventer and Chenard. The Examiner relies on the PD website for its statement that the most common type of parkinsonism is idiopathic Parkinson's disease, whose cause is unknown. However, the website does not provide any reasoning as to why the ordinarily skilled artisan might expect a therapeutic agent effective in the treatment of epileptic seizures would likewise demonstrate efficacy in the treatment of chorea and dystonia.

Thus, the combination of Leventer and Chenard and the PD website does not provide an implicit motivation to, or an explicit teaching of, employ(ing) a compound as defined in the instantly pending claim 35 to treat chorea or dystonia. Accordingly, Applicant respectfully requests that the instant rejection under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

This constitutes a request for any needed extension of time and an authorization to charge all fees therefor to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to deposit account No. 19-5117.

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Respectfully submitted,
/Marina Heusch/

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